Initial Approval Date: July 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Atopic Dermatitis Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Dupilumab (Dupixent®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a dermatologist or immunologist.[2,3]
- Patient must have had an adequate trial (at least 21 days) of or contraindication to all of the following: a topical calcineurin inhibitor and a phosphodiesterase-4 inhibitor.[2]
- Patient must have had an adequate trial (at least 8 weeks) of or contraindication to a systemic conventional agent listed in Table 2.[4]
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of the following criteria:[2,5,6]
    - Eczema Area and Severity Index (EASI) score of ≥ 16.[6]
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits for Atopic Dermatitis (AD).[6]

Medication	Indication(s)	Age	Dosing Limits
Interleukin-4 Receptor Antagonists			
Dupilumab (Dupixent®)	AD	≥ 12 years	Adults: 600 mg (given as two 300 mg injections) initially SC followed by 300mg every other week Ages 12 to 17 years: < 60 kg: 400 mg (given as two 200 mg injections) initially SC followed by 200mg every other week ≥ 60 kg: 600 mg (given as two 300 mg injections) initially SC followed by 300mg every other week

SC: subcutaneous

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Patient has documented response compared to baseline in at least one of the following measurements:[5]
    - EASI improvement ≥ 75% compared to baseline.[6]
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 MONTHS

Table 2. List of conventional therapy in the treatment of atopic dermatitis[1,7]

Topical		Systemic
Calcineurin Inhibitors	**PDE-4 Inhibitors**	**Systemic Conventional Agents**
Protopic® (tacrolimus 1% & 0.03%)	Eucrisa® (crisabole)	Gengraf®, Neoral® (cyclosporine)
Elidel® (pimecrolimus 1%)		Azasan®, Imuran® (azathioprine)
		Trexall®, Rheumatrex®, Otrexup®, Rasuvo® (methotrexate)
		CellCept®, Myfortic® (mycophenolate mofetil)

PDE-4: Phosphodiesterase-4 inhibitors

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Humira® (adalimumab)	Rituxan® (rituximab)
Amevive® (alefacept)	Hyrimoz™ (adalimumab-adaz)	Siliq® (brodalumab)
Amjevita™ (adalimumab-atto)	Ilaris® (canakinumab)	Simponi® (golimumab)
Cimzia® (certolizumab)	Ilumya™ (tildrakizumab-asmn)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Inflectra® (infliximab-dyyb)	Skyrizi™ (Risankizumab)
Cosentyx® (secukinumab)	Ixifi™ (infliximab-qbtx)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kevzara® (sarilumab)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Kineret® (anakinra)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Nucala® (mepolizumab)	Tysabri® (natalizumab)
Entyvio® (vedolizumab)	Olumiant® (baricitinib)	Xeljanz® (tofacitinib)
Erelzi™ (etanercept-szzs)	Orencia® (abatacept)	Xeljanz XR® (tofacitinib)
Eticovo® (etanercept-ykro)	Remicade® (infliximab)	Xolair® (omalizumab)
Fasenra™ (benralizumab)	Renflexis® (infliximab-abda)	

References

1. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol 2014; 71:116-32. Available at https://www.aad.org/practicecenter/quality/clinical-guidelines . Accessed 6/6/19.
2. Boguniewicz M, Fonacier L, Guttman-Yassky E, et al. Atopic dermatitis yardstick: practical recommendations for an evolving therapeutic landscape. Ann Allergy Asthma Immunol. 2018;120:10–22.e2. Available at https://www.annallergy.org/article/S1081-1206(17)31260-7/fulltext . Accessed 6/10/19.
3. Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part I. J Eur Acad Dermatol Venereol. 2018;32:657–682. Available at https://www.eadv.org/clinical-guidelines. Accessed 6/10/19.

4. Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part II. J Eur Acad Dermatol Venereol. 2018;32:850-878. Available at https://www.eadv.org/clinical-guidelines . Accessed 6/10/19.
5. Severity strata for Eczema Area and Severity Index (EASI), modified EASI, Scoring Atopic Dermatitis (SCORAD), objective SCORAD, Atopic Dermatitis Severity Index and body surface area in adolescents and adults with atopic dermatitis. British Journal of Dermatology 177.5 (2017): 1316-1321.
6. Dupixent (dupilumab) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc., Sanofi Genzyme; Mar 2019.
7. Current guidelines for the evaluation and management of atopic dermatitis: A comparison of the Joint Task Force Practice Parameter and American Academy of Dermatology guidelines. J Allergy Clin Immunol 2017;139(4)S49-S57. Available at https://www.sciencedirect.com/science/article/pii/S0091674917301495. Accessed on 6/6/19.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE